D. The Master Complaint

The named plaintiffs consist of nine individual Medicare Part B beneficiaries, four ERISA-qualified employee benefit plans, and twenty-one associations, which together allege payments for very few specific Medicare Part B drugs and no drugs outside of Medicare. With respect to Part B drugs, plaintiffs allege generally that defendants "artificially inflated" the prices provided to independent publishers by not reporting prices "reflect[ing] the actual pricing structure of the drugs." Cplt. ¶ 159. According to plaintiffs, defendants "knew that actual transaction price data – the amounts charged to providers and others for their drugs – was not publicly available, and they kept this information (on which AWPs should have been calculated) highly confidential and secret." Cplt. ¶ 136. Plaintiffs allege that defendants increased their market shares by touting the "spread" between the amount paid by the doctors and the amount reimbursed by Medicare as profit to the doctors. Cplt. ¶¶ 159-161.

In paragraphs 166-172 of the Master Complaint, plaintiffs conclusorily allege that the "AWP fraud strikes well beyond Medicare Part B, adversely impacting health plans and their participants with respect to purchases" of hundreds of unnamed "brand name drugs." Cplt. ¶166. (The defendants that manufacture only generic drugs are not included in these charges.) According to plaintiffs, health plans also rely on AWP in setting reimbursement rates for prescription drugs not covered by Medicare and sold through pharmacy benefit managers ("PBMs"). "Just as" physicians are alleged to be "incentivized" by the spread provided under the Medicare program, defendants are alleged to "incentivize PBMs to place the brand name drugs with the highest-inflated AWPs on the PBMs' formularies by marketing the spread" between the PBM acquisition price and the amounts paid by health plans and HMOs. Cplt.

¶ 171. Not a single example of this alleged practice is alleged anywhere in the 164-page Master Complaint, and not one PBM, health plan, HMO, or "brand name drug" is identified.[13]

Plaintiffs seek to represent two separate classes – (1) those individuals and "entities" that paid for a Part B drug ("Class 1"); and (2) "all Third-Party Payors" that contracted with a PBM "or other intermediary" to offer "brand name prescription drugs" based on AWP ("Class 2"). Cplt. ¶ 333. Plaintiffs allege that they made co-payments or other payments "based on" the published AWPs, and they seek to recover under RICO (Counts I-IV) and the consumer protection statutes of eleven states (Count V). Plaintiffs also seek declaratory relief that "setting stated reimbursement prices above the actual average wholesale price for" various drugs is unlawful (Counts VI-VII). Cplt. ¶¶ 458-465.

ARGUMENT

Plaintiffs' invitation to the Court to preempt the ongoing Congressional and regulatory review of AWP-based reimbursement faces at least three insurmountable obstacles. First, in view of the comprehensive public record and deliberate Medicare policy choices made by Congress and HHS, the Court cannot find that it was fraud for published AWPs to be well above provider acquisition cost. Second, plaintiffs' four RICO claims fail because the injuries alleged were not directly caused by defendants, the enterprise allegations are deficient, and the allegations of fraud fail to satisfy Rule 9(b). Finally, the state law claims are preempted by the Medicare Act and ERISA, and they also fail because fraud and proximate cause are not adequately alleged.

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[13] Curiously, the unidentified PBMs are labeled "Defendants," Cplt. ¶ 431(a)-(p), even though none are named in the list of defendants. Cplt. ¶¶ 51-130.

I. THIS CASE SHOULD BE DISMISSED BECAUSE THE COURT CANNOT FIND FOR PLAINTIFFS WITHOUT REJECTING AND REWRITING DELIBERATE MEDICARE POLICY CHOICES MADE BY CONGRESS AND HHS.

Plaintiffs' entire case is predicated on the basic contention that defendants were legally required to report AWPs at the providers' actual acquisition cost, or something close to that. *See* Cplt. ¶¶ 4, 5, 136, 159, 169, 388, 415, 442. Thus, each and every fraud and consumer deception claim in the Master Complaint flows from the core proposition that it was "fraud" to "report" allegedly "inflated" AWPs to third-party publishing services. Accordingly, plaintiffs' claims necessarily depend entirely on the Court's adoption of plaintiffs' interpretation of the term "AWP" as meaning the actual cost at which providers acquire drugs, or some close variant of that. The Court cannot make this finding for two reasons.

A. Plaintiffs' Assertion That AWP Approximates Actual Acquisition Cost Fails As A Matter Of Law.

Accepting (as we must in this motion) plaintiffs' unqualified allegation that virtually the entire pharmaceutical industry reported AWPs that were significantly higher than actual acquisition costs, such reporting could not have been fraudulent as a matter of law. Congress and HHS fully understood when incorporating AWP into the Medicare reimbursement system that the published AWPs for many drugs were significantly higher – and for some drugs several times higher – than the actual cost to providers.

First, there is no support in the AWP regulation or the Medicare statute for plaintiffs' interpretation of AWP as something akin to provider acquisition cost. Both HCFA and the GAO have confirmed that the term AWP is not defined by statute or regulation.[14]

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[14] *See* 63 Fed. Reg. 58,849 (Nov. 2, 1998) (according to HCFA, "the law does not define the term 'average wholesale price.'"); *Medicare Drug Reimbursements: A Broken System for* (continued...)

Second, HCFA knew that the term AWP referred to published prices that often substantially exceeded provider acquisition costs when it adopted AWP as the Medicare reimbursement benchmark in 1992. Indeed, HCFA adopted the AWP regulation specifically to accommodate the concerns of doctors who argued that they needed a premium on drugs to offset under-reimbursement for their professional services.

Third, Congress knew that published AWPs for many drug products substantially exceeded actual acquisition costs when it later codified AWP as the reimbursement standard and rebuffed repeated Administration proposals to change it. Congress knew this

- in 1997 when it rejected the Administration's proposed "actual acquisition cost" legislation and enacted the 95% of AWP standard;
- in 1998 and 1999, when it failed to adopt at least ten bills that would have reduced Medicare drug reimbursement to actual acquisition cost or 83% of AWP; and
- in 2000, when it passed BIPA to require HCFA to continue to use the AWPs published in industry publications as the basis of Medicare drug reimbursement.

Fourth, not only has Congress known that the published AWPs are often well above actual cost, it has made clear that the system, flawed though it may be, should not be changed by HHS or anyone else until certain competing Medicare policy issues are resolved. As of late 2002, Congress has yet to reconcile these important policy issues.

Lacking any support in the AWP regulation, the Medicare statute, or the legislative and regulatory history, and given the undisputed public record recited in the Statement of the Case,

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Patients and Taxpayers: Joint Hearing Before the Subcomm. on Health and the Subcomm. on Oversights and Investigations of the House Comm. on Energy and Commerce, 107th Cong. 34 (Sept. 21, 2001) (GAO official testifies that AWP "is not defined in law or regulation so the manufacturer is free to set an AWP at any level, regardless of the actual price paid by purchasers.") (Ex. 26).

the Court simply cannot find that AWP means anything close to provider acquisition cost or that it was fraudulent to report prices that were higher (even much higher) than provider acquisition costs.

B. Adopting Plaintiffs' Interpretation Of AWP Would Impermissibly Invade The Province Of The Legislative And Executive Branches.

In light of Congress' explicit decision to leave the AWP-based reimbursement system in place, the Court would exceed the limits of its jurisdiction and impermissibly invade the province of the elected branches by requiring the reporting of prices at or near actual acquisition cost. The Court cannot grant relief on any of plaintiffs' claims unless it rewrites the reimbursement rules that Congress and the Executive Branch put in place during the relevant period.

Prudential limitations on the exercise of Article III jurisdiction dictate that federal courts should not usurp congressional and executive branch policy choices when those governmental institutions "may be more competent to address" the policies at issue. *Warth v. Seldin*, 422 U.S. 490, 499-500 (1975); *cf. Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 866 (1984) ("[The] responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones."). Congress is not only competent to decide what rate the government will pay for Medicare covered drugs, it is currently engaged in heated debate over exactly this issue.

The doctrine of prudential abstention, as set forth in *Warth* and similar cases, is closely related to the political question doctrine, for both articulate separation of powers considerations. Of particular relevance to this case, "[t]he political question doctrine excludes from judicial review those controversies which revolve around policy choices and value determinations constitutionally committed for resolution to the halls of Congress or the confines of the

Executive Branch." *Japan Whaling Ass'n v. American Cetacean Soc'y,* 478 U.S. 221, 230 (1986); *see also Beacon Prods. Corp. v. Reagan*, 633 F. Supp. 1191, 1194 (D. Mass. 1986) ("The political question doctrine operates as a prudential limitation on the courts' review of other branches of government; it is 'primarily a function of the separation of powers.'"). At bottom, plaintiffs are trying through this litigation to change the Medicare reimbursement system by asking the Court to adopt some undefined market-based pricing benchmark. Congress explicitly barred HCFA from doing this after weighing the complex Medicare reimbursement and policy issues involved, and clearly the Court should not second guess Congress' judgment.

The decision in *Stephenson v. Shalala*, 87 F.3d 350 (9th Cir. 1996), demonstrates how principles of judicial deference warrant dismissal of an action challenging Medicare reimbursement standards. Plaintiffs in that case sought an order compelling HHS to enforce their interpretation of a provision in the Medicare Act governing Part B reimbursement for hospital services. *See id.* at 351-54. The Ninth Circuit dismissed the claims and "decline[d] the beneficiaries' invitation to preempt Congressional action in this very delicate area of public policy." *Id.* at 356. The Court listed three reasons for its deferral to Congress: (1) Medicare is an "enormously complicated" regulatory scheme; (2) Congress had participated in creating the reimbursement structure at issue; and (3) Congress was in the process of considering its own changes to the system. *Id.* All of those factors are present here.

As in *Stephenson*, plaintiffs seek to modify a key component of the "enormously complicated" Medicare drug reimbursement system. *Id.* "The [Medicare] system is a web; a tug at one strand pulls on every other," and, challenges to the system are better left to Congress and HHS to resolve. *Id.* This is particularly true in this case. If the Court redefines AWP as plaintiffs ask, this "tug" at the Medicare system will impact a significant Medicare "strand"– the

amount at which providers are reimbursed, which in turn helps cover under-reimbursed costs for physicians to treat patients in their offices. The Court should not venture into these complex Medicare policy issues, particularly as there are no judicially manageable standards to guide the Court in determining what the "correct" reimbursement levels should be. That is the province of Congress and HHS to resolve.[15]

II. PLAINTIFFS' FOUR RICO CLAIMS SHOULD BE DISMISSED.

In Counts I-IV, plaintiffs seek to enforce their policy views on prescription drug reimbursement through a federal racketeering case. The RICO claims should be dismissed because (A) plaintiffs cannot demonstrate violations of the mail and wire fraud statutes, which are the foundation for the RICO claims; (B) the plaintiffs' injuries were not caused directly by any conduct of the defendants; (C) the dozens of putative RICO enterprises fail as a matter of law; and (D) the plaintiffs have failed to allege fraud with the particularity required by Rule 9(b).

A. The RICO Claims Fail Because There Was No Fraud.

Plaintiffs' RICO claims are based on alleged predicate acts of mail and wire fraud. *See* 18 U.S.C. § 1341 (mail); 18 U.S.C. § 1343 (wire). Thus, without viable mail and wire fraud allegations, there can be no claim under RICO. *See Broderick v. Roache*, 751 F. Supp. 290, 294 (D. Mass. 1990). The mail and wire fraud statutes require that each defendant knowingly and willfully engage in a "scheme to defraud" using the interstate mails and wire communications in furtherance of that scheme. *See United States v. Cassiere,* 4 F.3d 1006, 1011 (1st Cir. 1993). Like common law fraud, mail and wire fraud requires deception "by means of false or fraudulent

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[15] Of course, if HHS does attempt to resolve the AWP issue with a rulemaking in 2002 or 2003, the agency's actions may be subject to further congressional action and judicial review.

pretenses, representations, promises, or other deceptive conduct.'" *Bonilla v. Volvo Car Corp.*, 150 F.3d 62, 66 (1st Cir. 1998).

As noted, the mail and wire fraud allegations depend entirely on the notion that it was fraud to submit pricing information to independent publishers that did not reflect providers' acquisition cost or something close to that. As demonstrated in Part I, it could not have been fraud to report prices that were above (even well above) "true market price" or "actual" provider acquisition cost. No fraud claim can survive in the face of two decades of government publications about what published AWPs meant.[16]

B. The Plaintiffs Cannot Show That The Defendants Directly Caused The Higher Drug Prices About Which They Complain.

The civil enforcement section of RICO provides a cause of action for persons injured in their "business or property by reason of a [RICO] violation." 18 U.S.C. § 1964(c) (emphasis supplied). Citing this language, the Supreme Court has held that it is not enough for the conduct at issue to be the "but for" cause of the injury; the violation must be the direct, proximate cause as well. *Holmes v. Securities Investor Prot. Corp.*, 503 U.S. 258, 265-66, 268 (1992); *see Camelio v. American Fed'n*, 137 F.3d 666, 670 (1st Cir. 1998) ("merely proving that the alleged predicate acts were a 'cause in fact' of plaintiff's injuries will not be sufficient."). For this reason, RICO plaintiffs may not recover if the causal connection is "too remote," *Holmes*, 503 U.S. at 271; if the connection between the injury and the conduct is "insufficiently close," *Camelio*, 137 F.3d at 670; or if plaintiff's loss was caused more directly by an intervening party. *Willis v. Lipton*, 947 F.2d 998, 1001 (1st Cir. 1991). In this case, the Master Complaint

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16 *See, e.g., Associates in Adolescent Psychiatry, S.C. v. Home Life Ins. Co.*, 941 F.2d 561, 571 (7th Cir. 1991); *Blount Fin. Servs., Inc. v. Walter E. Heller & Co.*, 819 F.2d 151, 153 (6th Cir. 1987); *Caraluzzi v. Prudential Secs., Inc.*, 824 F. Supp. 1206, 1212 (N.D. Ill. 1993).

demonstrates that plaintiffs' alleged injury – higher drug prices than they would like – was not caused directly by the alleged actions of the drug company defendants.

Unlike the typical civil RICO case, plaintiffs here are not alleged to have purchased anything from defendants. Defendants sell their products to physicians, other medical providers and wholesalers, not to Medicare beneficiaries. Cplt. ¶¶ 3, 4, 5, 132. At most, each plaintiff made – or in the case of the entity plaintiffs had a member or an insured who made – a Medicare co-payment to a physician for administering a drug that the physician allegedly purchased from either a wholesaler or from a defendant. Thus, the Medicare beneficiary plaintiffs and benefit plan plaintiffs are "indirect purchasers." *See Illinois Brick Co. v. Illinois*, 431 U.S. 720, 726 (1977).[17] The law is clear that indirect purchasers may not recover under civil RICO.[18]

In addition to plaintiffs' status as indirect purchasers, there are three significant intervening acts between their alleged injuries and the alleged acts of the defendants, making the causal chain extraordinarily attenuated.

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[17] In fact, in one of the original AWP cases subsequently transferred to this Court, the Medicare beneficiaries and employee benefit plan plaintiffs referred to themselves as indirect purchasers. *See* Amended Class Action Complaint ¶¶ 16-17, *Action Alliance of Senior Citizens of Greater Philadelphia, et al., v. SmithKline Beecham Corp.*, No. 01-CV-5790 (E.D. Pa. Jan. 10, 2002).

[18] *See, e.g., McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 848, 855 (3d Cir. 1996) ("The precepts taught by *Illinois Brick* . . . apply to RICO claims, thereby denying RICO standing to indirect victims.") (citation omitted); *County of Oakland v. City of Detroit*, 866 F.2d 839, 852 (6th Cir. 1989), *cert. denied*, 497 U.S. 1003 (1990); *Sperber v. Boesky*, 849 F.2d 60, 65 (2d Cir. 1988); *Carter v. Berger*, 777 F.2d 1173, 1175 (7th Cir. 1985) (indirect purchaser principles "should apply to RICO cases, not the least because the damages provision in [civil RICO] is practically verbatim the damages provision in the antitrust laws."); *Kaiser v. Stewart*, 965 F. Supp. 684, 688 (E.D. Pa. 1997) ("Indirect purchasers cannot recover money damages under either [civil RICO or the antitrust laws]."); David B. Smith & Terrance G. Reed, *Civil RICO* § 6.04(4)(a)(ii) (2001) ("One antitrust standing limitation that has been applied to RICO claims is the direct purchaser limitation.").

First, plaintiffs do not allege that defendants made a single misrepresentation to them. They allege, instead, that defendants made misrepresentations – in the form of inflated AWPs – to third-party price reporting services. Cplt. ¶¶ 134-36. Medicare and other payors, according to plaintiffs, then relied on the reported prices, which allegedly caused reimbursements and co-payments to be inflated, which caused injury to plaintiffs.

Second, under Medicare it is the prescribing doctor (or other provider), not the drug company, who sets the charge for drugs she administers and who submits claims for reimbursement to the Medicare carrier. Cplt. ¶ 133. The prescribing doctor may set her "actual charge" at any level, including a level below AWP. *See* 42 C.F.R. § 405.517(b) (Ex. 30) (total Medicare reimbursement is "the lower of the actual charge on the Medicare claim for benefits or 95% of the national average wholesale price") (emphasis added). When the doctor charges less than 95% of AWP, the beneficiary simply pays a co-payment equal to 20% of the doctor's "actual charge," not a higher co-payment amount that is based in any way on AWP. The provider's charging decision is therefore a critical intervening cause of plaintiffs' alleged injuries.

Third, and perhaps most significantly, it was Congress (in the case of Medicare) and the health plans (outside of Medicare, *i.e.*, with respect to Class 2) that chose to base drug reimbursement on AWP. Congress has always been free to base drug reimbursement amounts on something other than AWP – as it has done with respect to every federal program other than Medicare. Furthermore, Congress could have required no co-payment or it could have required a flat fee rather than a percentage of total reimbursement. Moreover, the health plans in Class 2 had unfettered discretion to base reimbursement on any non-AWP fee schedule or pricing system of their choosing. Thus the choices made by Congress and health plans to rely on AWPs were

the most fundamental "cause" of any injury to plaintiffs, and those choices were made without any involvement by any defendant.

These significant, independent, intervening causal events between defendant's alleged misreporting of AWPs and the amounts plaintiffs paid for drugs doom plaintiffs' RICO claim. Numerous cases hold that RICO claims may not be founded upon alleged misrepresentations when the plaintiff's injury stems from the intervening acts of others.[19]

C. Plaintiffs Do Not Allege A Viable RICO Enterprise.

"The central role" of the RICO enterprise, the Seventh Circuit has noted, "cannot be overstated. It is precisely the criminal infiltration and manipulation of organizational structures that created the problems which led to the passage of RICO." *United States v. Neapolitan*, 791 F.2d 489, 500 (7th Cir.), *cert. denied*, 479 U.S. 940 (1986). Recognizing the primacy of the enterprise requirement, plaintiffs present a dizzying array of putative RICO enterprises.

Each of the four RICO counts relies in part on a "Third Party Payor Enterprise" theory, in which each of the plaintiff employee benefit plans "constituted a separate RICO 'enterprise.'" Cplt. ¶ 351, 378, 405, 432. In addition, plaintiffs assert a variety of association in fact enterprises. In Count I, advanced on behalf of those who paid for Medicare Part B drugs (Class 1), plaintiffs allege a series of "AWP Enterprises," in which each defendant drug manufacturer is alleged to "associate in fact" with "various and independent" unnamed medical

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[19] *See, e.g., Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp.2d 460, 485 (D.N.J. 1998) (dismissing RICO claims where injuries result from "many intervening acts and causes" other than defendants' alleged misrepresentations); *Barr Labs., Inc. v. Quantum Pharmics, Inc.*, 827 F. Supp. 111, 113-16 (E.D.N.Y. 1993) (same); *Lifschultz Fast Freight, Inc. v. Consol. Freightways Corp.*, 805 F. Supp. 1277, 1291 (D.S.C. 1992) (rejecting RICO claim for lost profits based on alleged price-setting conspiracy because "[a]ny harm from the alleged conspiracy would be purely contingent on how the rate bureaus and the ICC acted based on the alleged predicate acts and then the customers' taking action based on the ICC action."), *aff'd* 998 F.2d 1009 (4th Cir.), *cert. denied*, 510 U.S. 993 (1993).

providers. Cplt. ¶¶ 346-50. In Count II, also asserted on behalf of Class 1, plaintiffs allege a "Publisher Enterprise" theory, consisting of separate associations in fact of "the various Publishers that reported AWPs for [Medicare] Covered Drugs" and each defendant. Cplt. ¶¶ 375-77. The Publisher Enterprise theory is also alleged in Count III, advanced on behalf of the Class 2 plaintiffs against various brand name prescription drug manufacturers. Cplt. ¶¶ 402-04. In Count IV, also asserted on behalf of the Class 2 plaintiffs against the brand name prescription drug defendants, the plaintiffs allege a "PBM Enterprise" theory, consisting of multiple association in fact enterprises of each brand name company and various pharmacy benefit managers ("PBMs") that "administered purchases" of the drugs manufactured by these defendants and "billed its members" for those products. Cplt. ¶¶ 429-31.

By defendants' count, these various theories present no fewer than 79 different enterprises. But the RICO enterprise requirement is not an invitation to offer up "alternative" enterprise theories in the hope that one might support a valid RICO claim.[20] Thus, several courts have rejected RICO claims founded upon "alternative" enterprise theories.[21] As one court observed, "The court cannot conceive of preparing a defense against these varied counts with their conclusory allegations of literally hundreds of possible [RICO] enterprises." *Olympia Brewing Co. Secs. Litig.*, No. 77-C-1206, 1984 WL 2140, at *7 (N.D. Ill. Dec. 18, 1984). Likewise, the RICO claims in this case plead so many enterprises that they strain credulity. And as demonstrated below, each enterprise theory fails as a matter of law.

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[20] *See* A. Mathews, et al., *Civil RICO Litigation* § 6.05, at 6-70 (2d ed. 1992) ("plaintiffs' search for an acceptable enterprise [sometimes] results in presenting a confusing array of alternative enterprise allegations, under the theory that the more seeds that are sown, the more likely it is that one will ultimately bear fruit.").

[21] *See, e.g.*, *Jennings v. Emry*, 910 F.2d 1434, 1439-40 (7th Cir. 1990); *Old Time Enters., Inc. v. Int'l Coffee Corp.*, 862 F.2d 1213, 1219 (5th Cir. 1989).

1. The Asserted "Associations in Fact" Did Not Function As A "Continuing Unit" Or With A "Common Purpose."

Three of plaintiffs' enterprise theories allege "association in fact" enterprises – the AWP, PBM, and Publisher Enterprise theories. The Supreme Court has held that an association in fact enterprise must be "an ongoing organization" whose members "function as a continuing unit" and are "associated together for a common purpose of engaging in a course of conduct." *United States v. Turkette*, 452 U.S. 576, 583 (1981). An association in fact enterprise must also have an existence "separate and apart from" the alleged pattern of racketeering activity. *Id.* A plaintiff must show that that the associated groups "constitute a larger unit, over and above their separate structures and operations." *Libertad v. Welch*, 53 F.3d 428, 442 (1st Cir. 1995). Thus, an association in fact enterprise must be a tightly organized unit with a defined hierarchy in which all members work in concert to achieve a common objective. None of plaintiffs' association in fact enterprises satisfy these criteria.

a. The AWP Enterprises

The AWP Enterprises are remarkably disparate groupings of each drug company defendant and the numerous unnamed physicians who prescribed that company's Medicare product(s). Cplt. ¶ 346. For example, the "Pfizer-Provider Enterprise" is an association in fact "consisting of the various and independent medical providers who prescribed Covered Drugs for which Pfizer reported an AWP, and Pfizer." *Id.* ¶ 350(q). Likewise, the "AstraZeneca Provider Enterprise" includes the company and the physicians who prescribed Zoladex and perhaps other products – *i.e.*, many of the nation's urologists. *Id.* ¶ 350(c). Each of these enterprises likely includes thousands of physicians around the country.

There is no set of facts under which such a large group could coalesce into a structured, organized, and hierarchical enterprise. Indeed, complaints alleging such vast and far-flung

enterprises are routinely dismissed.[22] Moreover, plaintiffs do not even allege that the AWP Enterprises have the requisite unified leadership and decision-making hierarchy. *See Libertad*, 53 F.3d at 443 (dismissing RICO claims based on association in fact enterprise theory because claims did not specifically allege facts demonstrating a common purpose or structure); *Simon v. Behavioral Health*, 208 F.3d at 1073, 1083 (9th Cir. 2000) (holding that at a minimum enterprise must have some sort of decision-making structure).[23]

The lack of any structure, organization, or common purpose is particularly obvious where, as here, the thousands of members of each enterprise are unknown to one another. Their only connection and common link is that they are doctors and they prescribed a particular company's drugs. This type of "hub" (drug company) and "spoke" (the doctors) association in fact fails as a matter of law.[24] Likewise, several cases have explicitly rejected the notion that

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[22] *See, e.g., Simon v. Behavioral Health*, 208 F.3d 1073, 1080-84 (9th Cir. 2000) (dismissing RICO claim where the alleged enterprise consisted of approximately 1,600 insurance companies, agents, trade groups, employee benefit plans, employers, and government entities that were alleged to have conspired to withhold benefits to patients); *Blue Cross & Blue Shield of Alabama v. Caremark, Inc.*, No. 98-C-1285, 1999 WL 966434, at *8 (N.D. Ill. Sept. 30, 1999) (dismissing RICO claim because plaintiff's enterprise allegations "fail to allege how this large and geographically diverse group of almost 3,000 independent physicians and entities acted in concert with one another" or had any ongoing structure).

[23] Another problem with the AWP Enterprise theory is that many physicians are part of multiple enterprises. Under plaintiffs' theory, a physician who prescribed product A would be in Company A's AWP Enterprise whereas if she prescribed product B, she would also be in Company B's AWP Enterprise. Thus, in the course of a business day, an oncologist who prescribed multiple Medicare-eligible products would find herself part of several different RICO enterprises, including enterprises in competition with each other. This cannot be taken seriously.

[24] *See, e.g., New York Auto. Ins. Plan v. All Purpose Agency & Brokerage, Inc.*, No. 97 Civ. 3164 (KTD), 1998 WL 695869, at *5 (S.D.N.Y. Oct. 6, 1998) (alleged "hub and spoke" conspiracy . . . is not . . . a RICO enterprise."); *First Nationwide Bank v. Gelt Funding Corp.*, 820 F. Supp. 89, 98 (S.D.N.Y. 1993) (finding alleged enterprise insufficient where defendant mortgage broker was "the 'hub,' and the various borrower defendants were the 'spokes'"), *aff'd* 27 F.3d 763 (2d Cir. 1994).

members of an association in fact enterprise share the requisite common purpose merely by participating in a particular industry or through a connection to a particular party or defendant.[25]

b. The Publisher Enterprises

The same infirmities fatally infect the Publisher Enterprises which consist of each defendant and "various Publishers that reported AWPs" for that company's Medicare-eligible drug products. Cplt. ¶ 375. Plaintiffs do not allege how a drug company and independent businesses that publish pricing information had a defined hierarchy or structure. Nor is it credible that these publishers had such a defined hierarchy and structure with more than thirty separate drug companies. The "common purpose" that allegedly binds these entities together is the "selling, purchasing, and administering" of Medicare drugs. *Id.* ¶¶ 375, 402. As noted, the courts require a far more tightly defined common purpose than participation in a common business venture like the reporting of drug prices. *See, e.g., SmithKline Beecham*, 62 F. Supp.2d at 553. Indeed, it is well settled that an enterprise cannot consist merely of two separate entities engaged in a common business venture.[26]

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[25] *See, e.g., Caremark*, 1999 WL 966434, at *8 (rejecting enterprise where "diverse group of almost 3,000 independent physicians and entities" lacked any common purpose); *Blue Cross of California v. SmithKline Beecham Clinical Labs, Inc.*, 62 F. Supp.2d 544, 552 (D. Conn. 1998) (rejecting "Billing Network" enterprise consisting of thousands of doctors and medical providers whose only connection was to defendant); *Gelt*, 820 F. Supp. at 98 (rejecting "Borrower Enterprise" because allegations that "disparate parties were associated in fact by virtue of their involvement in the real estate industry in the 1980s are insufficient to sustain a RICO claim"); *see also In re SmithKline Beecham Clinical Labs., Inc. Lab. Test Billing Practices Litig.*, 108 F. Supp.2d 84, 97 (D. Conn. 1999) (dismissing amended RICO complaint because "Laboratory Network" of 75-80 laboratories around the country did not share sufficiently specific common purpose).

[26] *See Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 41 n.7 (1st Cir. 1991) (banks and individuals engaged in the buying and selling of real estate did not constitute an enterprise because this theory fails to articulate how the defendants "comprised part on an 'ongoing organization' or 'function[ed] as a continuing unit.'") (quoting *Turkette*, 452 U.S. at 583); *see also VanDenBroeck v. Commonpoint Mortgage Co.*, 210 F.3d 696, 700 (6th Cir. 2000) (holding (continued...)

c. The PBM Enterprises

Plaintiffs' PBM Enterprise theory, which consists of each defendant that manufactures brand named drugs and various unnamed PBMs that administered the prescription drug benefits for various unnamed health plans, is plainly deficient. Plaintiffs do not even identify the PBM members of any of these putative enterprises, much less explain how the alleged enterprises could have displayed an ongoing structure, defined hierarchy or tightly defined common purpose. Nor would any such allegation be credible. The common purpose alleged – "selling, purchasing, and administering brand name drugs" – is again far too broad to satisfy the common purpose requirements imposed by *Turkette*. *See SmithKline Beecham*, 62 F. Supp.2d at 553.

2. The Third Party Payor Enterprise Theory Fails Because The Defendant Drug Manufacturers Did Not Participate In The "Operation or Management" Of These Independent Entities.

All four RICO claims also rely on the Third Party Payor enterprise theory, in which each plaintiff employee benefit plan constitutes a single entity enterprise whose affairs are alleged to have been separately conducted by each defendant through inflated AWPs. Cplt. ¶¶ 359, 386, 413, 440. Under Section 1962(c) of RICO, on which plaintiffs rely, a defendant must "conduct or participate" in the "affairs" of a distinct enterprise. 18 U.S.C. § 1962(c). The Supreme Court has held that, to "conduct or participate" in the affairs of an enterprise, a defendant must participate in its "operation or management." *Reeves v. Ernst & Young*, 507 U.S. 170, 185

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the defendant lender's relationship with the numerous secondary lenders to which it sold customer loans to be "too unstable and fluid an entity to constitute a RICO enterprise"); *Manhattan Telecomm. Corp. v. DialAmerica Mktg., Inc.*, 156 F. Supp.2d 376, 384 (S.D.N.Y. 2001) (dismissing RICO claims for lack of adequate allegations that defendants and their customers functioned as a continuing unit); *Moll v. U.S. Life Title Ins. Co.*, 654 F. Supp. 1012, 1032 (S.D.N.Y. 1987) (collection of attorneys, abstractors, and others engaged in real estate transactions did not constitute a RICO enterprise because there was no "continuity of structure or personnel").

(1993). The Court adopted its "operation or management" test to ensure that only persons that "exert control" or "direction" over the enterprise would be liable under the RICO statute. *Id.* at 178, 184. As one district court has noted, "the [*Reeves*] 'operation and management' test . . . is a very difficult test to satisfy." *LaSalle Nat'l Bank v. Duff & Phielps Credit Rating Co.*, 951 F. Supp. 1071, 1090 (S.D.N.Y. 1996).

It is especially difficult to satisfy the "operation or management" test when – as here – each defendant is a "complete outsider" to the enterprise. *Reeves*, 507 U.S. at 185. Indeed, as this Court has recognized, one of the only ways a "complete outsider" company could ever "operate or manage" another company would be if it were to "exert control" over that company by bribery or other covert means. *Bowdoin Constr. Corp. v. R.I. Hosp. Nat'l Bank, N.A.*, 869 F. Supp. 1004, 1009 (D. Mass. 1994) (Saris, J.). Put differently, "[a]bsent the involvement of an insider, it is difficult to conceive of conduct victimizing the enterprise as being participation in the conduct of its affairs." *See* A. Mathews, et al., *Civil RICO Litigation* § 7.03[A][2], at 7-57 (2d ed. 1992).

For this reason, it is not enough to allege that a defendant had a "business relationship" with the enterprise, "perform[ed] services" for the enterprise, or even victimized the enterprise. *Goren v. New Vision Int'l, Inc.*, 156 F.3d 721, 727-28 (7th Cir. 1998). "[N]ot even action involving some degree of decisionmaking constitutes participation in the affairs of the enterprise." *Univ. of Md. v. Peat, Marwick, Main & Co.*, 996 F.2d 1534, 1538-39 (3d Cir. 1993). Under *Reeves*, association with an enterprise does not suffice; only actual control over an enterprise will permit liability.

The Third Party Payor enterprise theory cannot succeed because it is predicated on an absurd notion – that more than thirty separate drug companies all "controlled" the operations of

independent employee benefit plans. Plaintiffs do not allege that a single defendant exercised control over each Third-Party Payor, much less that all the defendants did. Nor is there any allegation that any defendant co-opted any "insider" within any Third Party Payor.[27] Absent these allegations, the Third Party Payor Enterprise theory fails as a matter of law.

D. The Master Complaint Fails To Allege Fraud With The Particularity Required By Rule 9(b).

The RICO claims also should be dismissed because plaintiffs' fraud allegations fail to satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b). It is well-established that Rule 9(b) applies to civil RICO claims based on mail and wire fraud. *See Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 42 (1st Cir. 1991). The numerous Rule 9(b) deficiencies of the Master Complaint as to particular defendants are discussed in the memoranda filed by individual defendants. This memorandum discusses the pleading deficiencies of the Class 2 allegations against defendants that manufacture brand named drugs and the global allegations concerning drug samples and physician inducements.

1. The Class 2 Allegations Are Plainly Deficient.

Plaintiffs' most egregious generality is the sweeping allegation that defendants' alleged AWP fraud strikes "well beyond" the few Medicare Part B drugs that are identified in the Master Complaint. This allegation involves an entirely different group of drugs (hundreds, if not thousands of unidentified "brand name" drugs) sold in an entirely different way (through unidentified PBMs and "other intermediaries"), and paid for by an entirely different putative class (the hundreds, if not thousands, of separate health insurance plans that pay for prescription

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[27] Accordingly, this case is not like *Aetna Cas. Sur. Co. v. P & B Autobody*, 43 F.3d 1546, 1559-60 (1st Cir. 1994), where the Court of Appeals found that defendant outsiders participated in the operation or management of Aetna by co-opting, bribing, and co-conspiring with Aetna appraisers. There is no such allegation in this case.

drugs not covered by Medicare). Cplt. ¶¶ 166-72; 333. Class 2 purports to include more than 200 million Americans who purchase their prescriptions through PBMs. Cplt. ¶ 170.

The supposed "factual" basis for these sweeping allegations is contained in a few paragraphs of conclusory statements concerning how the "Defendant Drug Manufacturers" allegedly "marketed the spread" between the price at which PBMs allegedly pay for drugs and the allegedly "inflated" AWP rate at which health insurance plans allegedly chose to reimburse. Cplt. ¶¶ 166-72. Yet the following critical allegations about this sweeping new kind of "AWP fraud," are entirely absent:

- the identity of a single "brand name drug" manufactured by a single one of the multiple defendants that are subject to these allegations;
- identification of a single "brand name drug" that was allegedly paid for by a single one of the multiple named plaintiffs;
- the identity of a single PBM or "other intermediary" through which any defendant allegedly perpetrated this vast and sweeping alleged fraud, let alone allegations about the particulars of any such PBMs' involvement;
- a single specific allegation about how any defendant allegedly "inflated" a brand name drug's "AWP," or how a defendant allegedly "marketed the spread" to a PBM;
- a single specific allegation about any statement that any defendant made to any other party, let alone particulars about the time, place and manner of a single act or statement that constitutes the alleged "AWP fraud;" and
- a single specific allegation about how a single health insurance plan or other third party payor, including any of the named plaintiffs, was allegedly affected, let alone damaged, by this alleged scheme, let alone by the particular fraudulent acts of a particular defendant.

Without these very basic allegations, defendants have no idea what the "Class 2" "brand name" PBM claims are all about, let alone how to begin to mount a factual defense. Accordingly, all of the Class 2 claims should be dismissed.

2. The Allegations Pertaining To Improper Drug Samples And Physician Inducements Are Devoid Of Particulars.

The few allegations about improper "drug samples" and physician "inducements" also violate Rule 9(b). With respect to drug samples, plaintiffs allege generally that (1) "defendants" provided free samples of unspecified drugs to providers (which in and of itself is commonplace, of immense clinical and therapeutic value, and perfectly legal), (2) that "defendants" allegedly provided such unspecified samples "as a means of lowering the price," and (3) that "defendants" "specifically told providers to bill Plaintiffs and the members of the Class for the free samples, which Defendants knew was unlawful." Cplt. ¶ 162. These general allegations make no distinction between the legitimate provision of drug samples and specific instances in which samples were allegedly used as part of an "AWP Fraud" scheme. Moreover, although plaintiffs rely heavily on the criminal plea entered by TAP Pharmaceuticals to charges under the Prescription Drug Marketing Act – not RICO – that TAP encouraged physicians to bill for free samples, it is insufficient under Rule 9(b) simply to allege in conclusory fashion that any other defendant – let alone "Defendants" (plural) – also told physicians to bill for free samples.[28]

The Master Complaint further contains a sweeping general allegation that "Defendant Drug Manufacturers also have provided and/or arranged for many other non-public financial inducements to stimulate sales of their Covered Drugs" such as "volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and grants." Cplt. ¶ 165. This kind of all-inclusive allegation – entirely devoid of particulars as to which defendant was involved and what any defendant allegedly did, let alone any "time, place and manner"

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[28] TAP was dismissed from this action on November 12, 2002, by stipulation. Through a motion to strike, a number of defendants seek to have the allegations about TAP stricken from the Master Complaint.

allegations – is plainly insufficient. Rule 9(b) requires a plaintiff to connect specific allegations of fraud to each individual defendant and prohibits a plaintiff from merely grouping some or all defendants together in its fraud claim. *See, e.g., Luce v. Edelstein*, 802 F.2d 49, 54 (2d Cir. 1986). The failure of particularity is made even more egregious when plaintiffs combine allegations that are not directed at any identified defendant with sweeping and unparticularized allegations about a laundry list of alleged kinds of "inducements," again without particular examples or specifics.[29]

III. PLAINTIFFS' STATE LAW CLAIMS ARE PREEMPTED.

In Count V, plaintiffs allege claims under the unfair and deceptive practices statutes of eleven different states. To the extent individuals or entities that paid for prescription drugs through the Medicare program seek to recover those monies under these state statutes, those claims are preempted by the Medicare Act and its regulations. To the extent individuals (including Medicare beneficiaries) or entities that paid for prescription drug costs through an ERISA plan seek to recover those monies under the state statutes, those claims are preempted by ERISA.[30]

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[29] Plaintiffs' failure to plead the elements of a § 1962(c) claim dooms their RICO conspiracy claim in Count I. 18 U.S.C. § 1962(d). *See Miranda v. Ponce Fed. Bank*, 948 F.2d 41, 45 n.4 (1st Cir. 1991) (§ 1962(d) claim alleging conspiracy to violate § 1962(c) cannot be sustained when underlying § 1962(c) claim is invalid). Plaintiffs' conspiracy claim also fails because they have failed to allege that defendants "knowingly joined a conspiracy to violate § 1962(c)," *Aetna Cas. Sur.*, 43 F.3d at 1562, or to allege the circumstances surrounding the conspiracy. *See Doyle v. Hasbro, Inc.,* 103 F.3d 186, 190 (1st Cir. 1996) (affirming dismissal of RICO claim where complaint set forth conclusory allegations that the conspiracy existed). Accordingly, the § 1962(d) claim in Count I should be dismissed.

[30] Plaintiffs' state law claims should be dismissed for the reasons set forth in Point I, *supra*. If and when the Court needs to reach the complex Medicare and ERISA preemption issues summarized herein, defendants respectfully suggest that further briefing would be warranted and helpful.

A. The Medicare Act And Regulations Preempt Plaintiffs' State Law Claims.

Under the Supremacy Clause, a state law that conflicts with federal law is preempted. U.S. Const. art. VI, cl. 2. Absent express preemptive language from Congress, the Supreme Court has recognized two types of implied preemption: (a) "field" preemption; and (b) "conflicts" preemption. *Gade v. Nat'l Solid Wastes Mgmt. Assoc.,* 505 U.S. 88, 98 (1992); *see Massachusetts Assoc. of Health Maint. Orgs. v. Ruthardt*, 194 F.3d 176, 179 (1st Cir. 1999). The state law claims of the Class 1 plaintiffs are preempted by the Medicare Act on both grounds.

Congress' intent to preempt state law may be inferred under the doctrine of field preemption where "[the] scheme of federal regulation [is] so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Fidelity Fed. Sav. & Loan Ass'n v. De La Cuesta*, 458 U.S. 141, 153 (1982). In this case, plaintiffs seek to have state law determine how much Medicare should have paid providers and, consequently, how much plaintiffs' co-payments should have been. Congress, however, has completely occupied the field of Medicare drug reimbursement through pervasive, extensive and detailed statutes and regulations.

The Medicare Act provides that the determination of the amount of benefits payable under Part B shall be made by the Secretary. *See* 42 U.S.C. § 1395ff(a). The extensive statutory and regulatory framework for drug reimbursement is set forth in the Statement of the Case, *supra*. Moreover, Congress in 2000 passed BIPA to prohibit HCFA from changing this system of reimbursement. This pervasive statutory and regulatory framework, and Congress' decision to require Medicare to pay based on AWPs in industry publications, demonstrate a Congressional intent to occupy the field of drug reimbursement for Medicare beneficiaries. Indeed, when Congress passed BIPA to prevent HCFA from recasting AWP to more closely approximate

actual prices paid, Congress surely did not want fifty states' varying laws to determine a drug's AWP. In similar situations, courts have held that the Medicare statute and regulations preempt state law causes of action.[31] Accordingly, plaintiffs' state law claims are preempted under the theory of field preemption.

Even where Congress has not supplanted state law in a specific field, state law is preempted, under the doctrine of conflicts preemption, "to the extent that it actually conflicts with federal law." *Fidelity*, 458 U.S. at 153. In enacting BIPA, Congress intentionally created and maintained a system in which the AWPs published in industry compendia provide the benchmark for Medicare payment, despite the fact that those AWPs often substantially exceed the price paid by providers. In this case, plaintiffs are asking the Court under state laws – potentially fifty of them – to substitute different AWPs. This aim clearly conflicts with BIPA.[32]

B. ERISA Preempts The State Law Claims Of The ERISA Plan Plaintiffs And The Individual Plaintiffs Whose Co-Payments Were Made By An ERISA Plan.

Plaintiff employee benefit plans (the "Third-Party Payors") are each alleged to be an ERISA plan "entitled to bring suit in its own name pursuant to" ERISA. Cplt. ¶¶ 23-26. The state law claims of these ERISA plan plaintiffs (as they relate to both the Class 1 and Class 2

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[31] *See, e.g., Congress of California Seniors v. Catholic Healthcare West*, 87 Cal. App. 4th 491, 493 (2001) ("the field of Medicare provider cost reporting and reimbursement is so fully and completely occupied by federal law . . . that there remains no room for state action."); *see also Ruthardt,* 194 F.3d at 179-85 (Massachusetts law requiring Medicare supplemental insurers to offer unlimited outpatient prescription drug coverage was preempted because Congress intended to create an exclusive federal regulatory scheme for prescription drug coverage).

[32] This case is distinguishable from *Massachusetts Medical Soc'y v. Dukakis,* 815 F.2d 790 (1st Cir. 1987), where the court held that a state statute forbidding doctors from charging Medicare beneficiaries more than the "reasonable charges" allowed by Medicare was not preempted. The state statute in that case had no bearing on how much the Medicare program paid; it dealt solely with how much additional money physicians could collect from their patients. Here, plaintiffs' state law claims directly implicate how much the Medicare program pays and therefore are preempted.

claims) and the state law claims of any Class 1 Medicare beneficiary plaintiff whose co-payment was made by an ERISA plan are preempted by ERISA.

ERISA specifically provides that it "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a) (emphasis added). Because the words "relate to" are intended to apply in their broadest sense,[33] ERISA preemption extends to any state cause of action that has a "connection or reference to" an ERISA plan. *Central States, S.E. & S.W. Welfare Fund v. Neurobehavioral Assocs.*, 53 F.3d 172, 174 (7th Cir. 1995). There are several respects in which plaintiffs' state law claims meet this test.

First, the state law claims concern the determination of the correct amount of benefits under the ERISA plans, which is "a central matter of plan administration" and a "core ERISA concern." *Egelhoff v. Egelhoff,* 532 U.S. 141, 148 (2001). The state law claims directly implicate the requirement that ERISA plans "specify the basis on which payments are made to and from the plan." 29 U.S.C. § 1102(b)(4).

Second, the "court's inquiry must be directed to the plan" to resolve the claim. *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 139-40 (1990). Under federal law, each ERISA-qualified plan must issue a "summary plan description," 29 U.S.C.§ 1022(a), which is considered part of the ERISA plan. *See Barker v. Ceridian Corp.*, 122 F.3d 628 (8th Cir. 1997). The summary plan description "shall" contain information about "eligibility for participation and benefits." 29 U.S.C. § 1022(b). Department of Labor regulations further provide that the summary plan description "shall include a description of: any cost-sharing provisions, including premiums, deductibles, coinsurance, and copayment amounts for which the participant or beneficiary will be

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[33] *See Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 98 (1983); *Hampers v. W.R. Grace & Co., Inc.*, 202 F.3d 44, 49 (1st Cir. 2000).

responsible . . . [and] whether, and under what circumstances, existing and new drugs are covered under the plan[.]" 29 C.F.R. § 2520.102-3(j)(3) (2002) (emphasis added).

Consistent with these requirements, the ERISA plans and related plan documents of the Third Party Payor plaintiffs (and the plans that paid the co-payments for the Medicare beneficiaries) will contain provisions about the conditions under which prescription drugs may be covered and the extent to which co-payments and deductibles may apply for such coverage. These plans will determine, for example, if reimbursement for prescription drugs for a particular employer is based on AWP, provider acquisition cost, or some other formulation entirely, such as a negotiated discount for the particular product, which is common in the industry. Alternatively, some of these plans may provide that a participant need pay only a flat fee for particular product, rather than a percentage of some calculated rate, whether based on AWP or not. In sum, these plans will determine which drugs are covered and the criteria for coverage and payment. Because the court will inevitably need to consult the terms of the ERISA plans to determine whether and how certain plaintiffs were injured, the state law claims are preempted.[34]

Third, the state law claims are preempted because they interfere with ERISA's objective of nationally uniform plan administration. *See Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 9 (1987). If the laws of fifty states were to determine how much ERISA plans should pay for a drug with a given AWP (when that ERISA plan pays based on AWP), then ERISA plan administrators would be subject to fifty different standards as they administer ERISA plans. In addition, beneficiaries of the very same ERISA plan who happen to live in different states would

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[34] *See Harris v. Harvard Pilgrim Health Care, Inc.*, 208 F.3d 274, 281 (1st Cir. 2000) ("ERISA will be found to preempt state-law claims if the trier of fact necessarily would be required to consult the ERISA plan to resolve the plaintiff's claims."); *Carlo v. Reed Rolled Thread Die Co.*, 49 F.3d 790 (1st Cir. 1995) (same); *Vartanian v. Monsanto Co.*, 14 F.3d 697 (1st Cir. 1994) (same).

be entitled to different benefits as a result of varying state law. This interferes with the ERISA objective of nationally uniform plan administration and benefits determinations. *See id.*

The state law claims of the ERISA plans and ERISA plan participants in this case are similar to those found to be preempted in other cases where such parties sought to recover alleged overpayments.[35] Accordingly, these claims should be dismissed.[36]

CONCLUSION

For the reasons stated above, the Master Consolidated Class Action Complaint should be dismissed.

Respectfully submitted,
ON BEHALF OF THE FOLLOWING
LISTED DEFENDANTS

[Original signature on file with the Court]

By: _____

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[35] *See Central States,* 53 F.3d at 174; *Kentucky Laborers Dist. Council Health and Welfare Fund v. Hope*, 861 F.2d 1003, 1005 (6th Cir. 1988); *In re SmithKline Beecham Clinical Laboratories, Inc. Lab. Test Billing Practices Litig.*, 108 F. Supp.2d at 109-12; *Davis v. SmithKline Beecham Clinical Laboratories, Inc.*, 993 F. Supp. 897, 899 (E.D. Pa. 1998).

[36] In addition to being preempted, plaintiffs' state law claims also fail for many of the same reasons as their RICO claims – failure adequately to plead either fraud or proximate causation.

ABBOTT LABORATORIES

AMGEN INC.

ASTRAZENECA PHARMACEUTICALS L.P.

AVENTIS BEHRING, LLC

AVENTIS PHARMACEUTICALS, INC.; HOECHST MARION ROUSSEL, INC.

BAXTER INTERNATIONAL, INC.; BAXTER HEALTHCARE CORPORATION

BAYER CORP.

BOEHRINGER INGELHEIM CORP.; BEN VENUE LABORATORIES, INC.

DEY, INC.

FUJISAWA HEALTHCARE, INC.; FUJISAWA U.S.A., INC.

SMITHKLINE BEECHAM CORPORATION, D/B/A GLAXOSMITHKLINE

HOFFMANN -LA ROCHE INC.

IMMUNEX CORPORATION

JOHNSON & JOHNSON; CENTOCOR, INC.; ORTHO BIOTECH PRODUCTS, LLP

MERCK & CO., INC.

PFIZER, INC.

PHARMACIA CORPORATION; PHARMACIA & UPJOHN, INC.

SCHERING-PLOUGH CORPORATION; WARRICK PHARMACEUTICALS CORPORATION

SICOR INC.; GENSIA, INC.; GENSIA SICOR PHARMACEUTICALS, INC.

WATSON PHARMA, INC.

Dated: November 25, 2002

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Consolidated Memorandum in Support of Defendants' Motion to Dismiss The Master Consolidated Class Action Complaint and the Revised Appendix of Exhibits was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on November 25, 2002, a copy to Verilaw Technologies for posting and notification to all parties.

Juliet S. Sorensen